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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,825	10/18/2000	Dario C. Altieri	044574-5022-2	3716

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/31/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/690,825

Applicant(s)
Altieri

Examiner
Karen Canella

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1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18, and 80-104 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17, 18, 80-93, and 97 is/are allowed.
- 6) ☒ Claim(s) 94-96 and 98-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Sep 26, 2002 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 1-8, 19-38 and 41-79 have been canceled. Claims 17, 18 and 80 have been amended. Claims 83-104 have been added. Claims 17, 18 and 80-104 are under consideration.
3. Claims 94, 103 and 104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 94 contains the embodiment of a “fusion protein” and is dependent on claim 93 which recites the embodiment of a heterologous amino acid sequence. It is unclear how recitation of a “fusion protein” in claim 94 further limits the metes and bounds of claim 93 drawn to a polypeptide further comprising a heterologous amino acid sequence.

The recitation of “immunogenic” composition does not further limit the composition of claim 103 without an additional embodiment that would narrow the metes and bounds of said composition. Furthermore, without recitation of a host animal in which the composition is to be immunogenic, the metes and bounds of the claims cannot be determined as any protein or peptide can be immunogenic in a host animal which would recognize an epitope of said protein or peptide as a “non-self” epitope.
4. Claims 95, 96 and 98-104 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a genus of proteins as they encompass proteins which vary from SEQ ID NO:3 and 34. The statement on page 18, lines 11-15 of the specification that “the survivin proteins of the instant invention include conservative

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variants which do not adversely affect the ability of the survivin protein to bind a survivin partner or to inhibit cellular apoptosis” do not constitute a definition of a survivin protein, nor a limitation that is applied to the claims. The claims do not provide guidance regarding structural attributes that determine if a protein qualifies as a “survivin” protein. The qualifier that the protein inhibits cellular apoptosis does not help in this regard as any protein which would inhibit cellular apoptosis would not be excluded from this genus. The specification describes only SEQ ID NO:3 and SEQ ID NO:34. Further, it appears that the binding partner of survivin is undisclosed, therefore one of skill in the art cannot determine if a protein sequence is a survivin protein sequence by testing binding of a putative survivin protein with a binding partner. Claims 98 and 99 specify amino acid residues where amino acid residues can be exchanged. However, the specification or claims do not limit the total number of amino acid substitutions, therefore claim 98 and 99 encompasses a large genus of amino acid sequences, and the recitation in the preamble of a “survivin polypeptide” cannot exclude an amino acid sequence from the genus as there is no limitation in claim 98 for the function of the survivin polypeptide. The instant claims lack adequate written description as SEQ ID NO:3 and SEQ ID NO:34 do not adequately represent the genus of proteins and peptides claimed.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
December 30, 2002


ANTHONY C. CAPUTA
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